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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/201,916	12/01/98	HOPE R	DYOU17.001AU

020995 HM22/1208
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EXAMINER	
ZEMAN, R	
ART UNIT	**PAPER NUMBER**
1645	14

DATE MAILED: 12/08/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/201,916	Applicant(s) Hope et al.
	Examiner Robert A. Zeman	Group Art Unit 1645

☒ Responsive to communication(s) filed on *Dec 1, 1998* .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-7, 17, and 18* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-7, 17, and 18* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

The election of Group I (claims 1-7 and 17-18), **without traverse**, in Paper No. 13 is acknowledged. Claims 8, 10-16 and 19-21 have been canceled. Claims 1-7 and 17-18 are pending and currently under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 and 6-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the targeting sequence comprising a hepatitis C virus (HCV) core protein and the targeting sequence comprising amino acids 125-144 and 161-166, does not reasonably provide enablement for "all fragment, derivatives, variants, or homologues thereof". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification fails to teach how to make and any HCV core protein derivatives, variants or homologues. The specification merely states that they may be used. Additionally, the specification only teaches how to use two HCV core protein fragments: positions 125-144 and 161-166 of the HCV core protein amino acid sequence. Consequently it

would be impossible for one of skill in the art to ascertain how to make and use the claimed invention.

Claims 1-7 and 17-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of identifying a substance which disrupts the interaction between a lipid globule targeting sequence and a lipid globule and determining whether said substances reduces or abolishes the susceptibility of **liver cells** to **hepatitis C virus (HCV)** or the effects of HVC infection on said cells , does not reasonably provide enablement for determining whether said substance reduces or abolishes the susceptibility of any other viral infection in any other cell type. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The specification discloses that the HCV core protein binds with lipid globules resulting in the diffusion of the lipid granules present in liver cells. The specification also discloses an inferred relationship between ADRP and lipoproteins in liver cells based on the observation that an increased level of HCV core protein results in a reduced level of ADRP. Based on this information the Applicant concludes that the disruption of the interaction between the lipoproteins and the HCV core protein would reduce the effects of HCV infections. The specification does not disclose a similar relationship between proteins of any other virus and lipoproteins and/or ADRP. Consequently it would be impossible for anyone to practice the claim invention.

Claims 5 and 17-18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The aforementioned claims are drawn to a method of identifying substances that treat or prevent a viral infection by upregulating the expression of adipocyte-specific differentiation related protein (ADRP) in mammalian cell. People of skill in the art require factual evidence, that a benefit can be derived by the therapeutic application of a substance. The instant specification fails to provide any evidence that any substance identified by methods instantly disclosed, would prevent or elicit a therapeutic response in a viral infection. Moreover, that ADRP levels in fact play a role in viral infections or disease progression. Since neither the art nor the specification indicates that any benefit to the treated subject would be obtained from substances identified by the claimed method, it would be impossible for one skilled in the art to which it pertains, or with which it is most nearly connected, to practice the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1- 7 and 17-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3 and 6-7 are rendered vague and indefinite by the use of the terms "derivatives", "homologues", and "variants". Applicant fails to define what is meant by a "variant". The specification is silent on what percentage of divergence is required to be considered a variant and at what point does a "variant" become totally unrelated. The specification is equally deficient in defining what is meant by a "variant", "derivative" or "homologue". Applicant fails to disclose what percentage of the total protein must be present in order for a polypeptide to be considered a "variant" or "derivative" of said HCV protein or what processes must be utilized to generate "derivatives" or "homologues" of said HCV protein. Additionally, the specification is silent with regard to what biochemical/immunological/physical properties must be present in order for a protein be considered a "variant", "derivative" or "homologue". Consequently, it would be impossible for one of skill in the art to ascertain what would fall under the categories of "variant", "derivative" or a "homologue".

Claim 1 is rendered vague and indefinite by the use of the term "capable of". Having the capacity to perform a function does not mean it is performed. Consequently, it is impossible to determine the metes and bounds of the claimed invention.

Claim 1 is rendered vague and indefinite by the use of the term "affecting". It is unclear what effects on a viral infection is encompassed by this limitation. Does affecting mean enhancing? limiting? preventing? Abrogating? As claimed it is impossible to determine the metes and bounds of the claimed invention.

Claim 2 is rendered vague and indefinite by the use of the term "expressed". Is said lipid globule targeting sequence normally expressed in the cell or is said expression due to the use of recombinant techniques? As written it is impossible to determine the metes and bounds of the claimed invention.

Claims 2 and 3 are rendered vague and indefinite by the use of the term "administered". It is unclear what methodologies are employed in order to "administer" a substance to cells. Is said "administering" done *in vivo* or *in vitro*? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 3 is rendered vague and indefinite by the use of the term "administering". It is unclear what methodologies are employed in order to "administer" a virus to cells. Is said "administering" merely contacting a virus with a cell? For what period of time? Is said "administration done *in vivo* or *in vitro*? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 3 is rendered and vague and indefinite by the use of the phrase "the susceptibility of the cell to viral infection or the effects of viral infection". What effects of viral infection is Applicant referring to? The onset of the disease state? Presence of a viral protein? Viral replication? Additionally. what is the criteria for determining when a cell is "infected"? Are said determinations done *in vivo* or *in vitro*? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 4 is rendered vague and indefinite by the use of the term "and/or". Is the targeting sequence in the "and" situation comprised of one polypeptide with a sequence of amino acids 125 to 144 and 161 to 166 of the HCV core protein or **two separate and distinct** polypeptides? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claims 5 and 17-18 are rendered vague and indefinite for failing to recite the active method steps required to perform the claimed invention.

Conclusion

No claim is allowed.

Claims 1-7 and 17-18 are free of the art of record

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991. The examiner can be reached between the hours of 7:30 am and 4:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, Donna Wortman, Primary Examiner can be reached at (703) 308-1032 or the examiner's supervisor, Lynette Smith, can be reached at (703)308-3909.

Robert A. Zeman

December 7, 2000

DONNA WORTMAN
PRIMARY EXAMINER